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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,691	11/12/2003	Andrew Robert Davids	674582-2001	5783

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,691	DAVIDS ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Application is a CIP of PCT/GB03/01851 filed April 30, 2003 and claims foreign priority to Application No. 0209884, filed April 30, 2002, in the United Kingdom.

Claims 1-77 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 10-15, 16, 20, 21, drawn to a polypeptide or peptide comprising the amino acid sequence in SEQ ID NO. 16 or SEQ ID NO. 26, and the ligand or compound that increases or decreases the level of expression or activity of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350+.

II. Claims 4-9, 17-19, drawn to a purified nucleic acid molecule as recited in SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25 or is a redundant equivalent or fragment thereof, the vector comprising the sequences, and the host cell transformed with the vector, classified in class 435, subclass 320.1.

III. Claims 22-30, drawn to a method of diagnosing a disease in a patient comprising comparing the level of expression a natural gene which encodes a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26 to a control level, wherein a level that is different to the control level is indicative of disease, classified in class 536, subclass 23.1.

IV. Claims 22-30, drawn to a method of diagnosing a disease in a patient comprising comparing the level of expression or activity of a polypeptide of

SEQ ID NO. 16 or SEQ ID NO. 26 to a control level, wherein a level that is different to the control level is indicative of disease, classified in class 536, subclass 23.1

V. Claim 31, drawn to a method of using a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26 as an antagonist of cytokine expression and/or secretion, classified in class 530, subclass 350+.

VI. Claims 32, 38, drawn to a pharmaceutical composition and a vaccine composition comprising a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350+.

VII. Claims 33-35, 39, drawn to a pharmaceutical composition and a vaccine composition comprising a nucleic acid molecule of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, a vector, and a host cell, classified in class 435, subclass 320.1.

VIII. Claim 40, 44, 45, drawn to a method of using a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, a ligand, or a compound, in the manufacture of a medicament for the treatment of an autoimmune disease, viral or acute liver disease, including alcoholic liver failure, or inflammatory disease, classified in class 530, subclass 350+.

IX. Claims 41-43, drawn to a method of using a nucleic acid of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, the vector, and the host cell, in the manufacture of a medicament for the treatment of an

autoimmune disease, viral or acute liver disease, including alcoholic liver failure, or inflammatory disease, classified in class 536, subclass 23.1.

X. Claim 46, drawn to a method of using a pharmaceutical composition in the manufacture of a medicament for the treatment of an autoimmune disease, viral or acute liver disease, including alcoholic liver failure, or inflammatory disease, classified in class 514, subclass 44.

XI. Claim 47-49, 59-64, drawn to a method of treating a disease in a patient, comprising administering to the patient a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350.

XII. Claims 50-58, drawn to a method of treating a disease in a patient, comprising administering to the patient a nucleic acid of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, a vector, or a host cell transformed with a vector, classified in class 536, subclass 23.1 or in class 424, subclass 93.1+.

XIII. Claims 65-67, drawn to a method of treating a disease in a patient, comprising administering to the patient a pharmaceutical composition, classified in class 530, subclass 350 or class 424, subclass 93.1+.

XIV. Claim 68, drawn to a method of monitoring the therapeutic treatment of disease in a patient, comprising monitoring the expression level or activity of a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350.

XV. Claim 69, drawn to a method of monitoring the therapeutic treatment of disease in a patient, comprising monitoring the expression level of a nucleic acids of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, classified in class 536, subclass 23.1.

XVI. Claim 70, drawn to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease, comprising contacting a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350+.

XVII. Claim 71, drawn to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease, comprising contacting a nucleic acid sequence of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, classified in class 536, subclass 23.1.

XVIII. Claims 72-74, drawn to a kit to used diagnose a disease comprised of nucleic acids that hybridize with nucleic acids of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, classified in class 536, subclass 23.1.

XIX. Claim 75, drawn to a kit of one or more antibodies that bind to a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, and a reagent used to detect the binding reaction between antibody and polypeptide, classified in class 424, subclass 130.1+.

XX. Claims 76, 77, drawn to a transgenic or knockout non-human animal, with higher, lower, or absent levels of polypeptide of SEQ ID NO. 16 or SEQ ID

NO. 26 and the method of using the animal to screen for compounds to treat disease, classified in class 800, subclass 3 and 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is to a polypeptide or peptide comprising the amino acid sequence in SEQ ID NO. 16 or SEQ ID NO. 26, and the ligand or compound that increases or decreases the level of expression or activity of SEQ ID NO. 16 or SEQ ID NO. 26. Invention II is to a purified nucleic acid molecule as recited in SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25 or is a redundant equivalent or fragment thereof, the vector comprising the sequences, and the host cell transformed with the vector. Invention I does not depend on Invention II to function and vice versa.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the while the different inventions are to a method of diagnosing a disease in a patient, Invention III is to comparing the level of a gene expression and Invention IV is to comparing the level of protein expression or activity of a protein. Invention III does not depend on Invention IV to function and vice versa.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the while the different inventions are to a pharmaceutical composition and a vaccine composition, Invention VI is comprised of a polypeptide and Invention VII is comprised of a nucleic acid molecule. Invention VI does not depend on Invention VII to function and vice versa.

Inventions VIII, IX, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, while the different inventions are to a method of using a compound in the manufacture of a medicament in the treatment of an autoimmune disease, viral or acute liver disease, including alcohol liver failure, or inflammatory disease, the compounds are unique and distinct and require different methods and reagents when being used. Invention VIII is to a polypeptide, Invention IX is to a nucleic acid, and Invention X is to a pharmaceutical composition. None of these Inventions depend on the others to function.

Inventions XI, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case while the different inventions are to a method of treating a disease in a patient, Invention XI comprises administering a polypeptide, Invention XII

comprises administering a nucleic acid, and Invention XIII comprises administering a pharmaceutical composition. None of these Inventions depend on the others to function.

Inventions XIV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case while the different inventions are to a method of monitoring the therapeutic treatment of disease in a patient, Invention XIV comprises monitoring the expression level or activity or activity of a polypeptide and Invention XV comprises monitoring the expression level of a nucleic acid. Invention XIV does not depend on XV to function and vice versa.

Inventions XVI and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case while the different inventions are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease, Invention XVI comprises contacting a polypeptide and Invention XVII comprises contacting a nucleic acid. Invention XVI does not depend on Invention XVII to function and vice versa.

Inventions XVIII and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case while the different inventions are to kits, Invention XVIII is to a kit that diagnoses a disease, using nucleic acids and Invention XIX is to a kit comprised of antibodies. Invention XVIII does not depend on Invention XIX to function and vice versa.

Inventions VI/VII, VIII/IX/X, and XI/XII/XIII are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions I/II and II/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In addition to being used to diagnose a disease in a patient, Inventions I/II can be used in a pharmaceutical composition.

Inventions I/II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). Invention II is to nucleic acids which are materially different and unrelated to Inventions I and V. Invention I can be used in a pharmaceutical composition and a vaccine composition.

Inventions I/II and VI/VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Inventions I/II can be used in a method of diagnosing a disease in a patient.

Inventions I/II and VIII/IX/X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Inventions I/II can be used in a method of diagnosing a disease in a patient.

Inventions I/II and XI/XII/XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Invention I/II can be used in a method of diagnosing a disease in a patient.

Inventions I/II and XIV/XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Invention I/II can be used in a method of diagnosing a disease in a patient.

Inventions I/II and XVI/XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Invention I/II can be used in a method of diagnosing a disease in a patient.

Inventions I/II and XVIII/XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Invention I/II can be used in a pharmaceutical composition.

Inventions I/II and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions I/II are to polypeptides and nucleic acids. Invention XX is to a transgenic

animal with higher, lower, or absent levels of polypeptide. The methods used to study Inventions I/II are materially different from those that are used to study Invention XX.

Inventions III/IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III/IV are to method of diagnosing a disease in a patient. Invention V is to a method of using a polypeptide as an antagonist of cytokine expression and/or secertion. Invention III/IV does not depend on Invention V to function and vice versa.

Inventions III/IV and VI/VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III/IV are to method of diagnosing a disease in a patient. Invention VI/VII is to a pharmaceutical composition and a vaccine composition. Inventions III/IV do not depend on Inventions VI/VII to function and vice versa.

Inventions III/IV and VIII/IX/X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III/IV are to method of diagnosing a disease in a patient. Inventions VIII/IX/X are to a method of using a pharmaceutical composition in the manufacture of a medicament. Inventions III/IV do not depend on Inventions VIII/IX/X to function and vice versa.

Inventions III/IV and XI/XII/XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III/IV are to method of diagnosing a disease in a patient. Inventions XI/XII/XIII are to a method of treating a disease in a patient. Inventions III/IX do not depend on Inventions XI/XII/XIII to function and vice versa.

Inventions III/IV and XIV/XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III/IV are to method of diagnosing a disease in a patient. Inventions XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Inventions III/IV do not depend on Inventions XIV/XV to function and vice versa.

Inventions III/IV and XVI/XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III/IV are to method of diagnosing a disease in a patient. Inventions XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease. Inventions III/IV do not depend on Inventions XVI/XVII to function and vice versa.

Inventions III/IV and XVIII/XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Inventions XVIII/XIX can be used in a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease.

Inventions III/IV and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III/IV are to method of diagnosing a disease in a patient. Invention XX is to a transgenic knockout non-human animal. Inventions III/IV do not depend on Invention XX to function and vice versa.

Inventions V and VI/VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is to the method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Invention VI/VII is to a pharmaceutical composition and a vaccine composition. Invention V does not depend on Inventions VI/VII to function and vice versa.

Inventions V and VIII/IX/X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is to the method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Inventions VIII/IX/X are to a method of using a

pharmaceutical composition in the manufacture of a medicament. Invention V does not depend on Invention VIII/IX/X to function and vice versa.

Inventions V and XI/XII/XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is to the method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Inventions XI/XII/XIII are to a method of treating a disease in a patient. Invention V does not depend on Invention XI/XII/XIII to function and vice versa.

Inventions V and XIV/XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is to the method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Inventions XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Invention V does not depend on Inventions XIV/XV to function and vice versa.

Inventions V and XVI/XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is to the method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Inventions XVI/XVII are to a method for

identifying a compound that is effective in the treatment and/or diagnosis of a disease. Invention V does not depend on Inventions XVI/XVII to function and vice versa.

Inventions V and XVIII/XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is to the method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Inventions XVIII/XIX are to a kit used to diagnose a disease and a kit to identify polypeptides. Invention V does not depend on Inventions XVIII/XIX to function and vice versa.

Inventions V and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is to the method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Invention XX is to a transgenic or knockout non-human animal. Invention V does not depend on Invention XX to function and vice versa.

Inventions VI/VII and XIV/XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VI/VII are to a pharmaceutical composition and a vaccine composition. Invention XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Inventions VI/VII do not depend on Inventions XIV/XV to function and vice versa.

Inventions VI/VII and XVI/XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VI/VII are to a pharmaceutical composition and a vaccine composition. Inventions XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease. Inventions VI/VII do not depend on Inventions XVI/XVII to function and vice versa.

Inventions VI/VII and XVIII/XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VI/VII are to a pharmaceutical composition and a vaccine composition. Inventions XVIII/XIX are to a kit used to diagnose a disease and a kit to identify polypeptides. Inventions VI/VII do not depend on Inventions XVIII/XIX to function and vice versa.

Inventions VI/VII and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VI/VII are to a pharmaceutical composition and a vaccine composition. Invention XX is to a transgenic or knockout non-human animal. Inventions VI/VII do not depend on Invention XX to function and vice versa.

Inventions VIII/IX/X and XIV/XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VIII/IX/X are to a method of using a pharmaceutical composition in the manufacture of a medicament. Invention XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Inventions VIII/IX/X do not depend on Inventions XIV/XV to function and vice versa.

Inventions VIII/IX/X and XVI/XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VIII/IX/X are to a method of using a pharmaceutical composition in the manufacture of a medicament. Inventions XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease. Inventions VIII/IX/X do not depend on Inventions XVI/XVII to function and vice versa.

Inventions VIII/IX/X and XVIII/XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VIII/IX/X are to a method of using a pharmaceutical composition in the manufacture of a medicament. Inventions XVIII/XIX are to a kit used to diagnose a disease and a kit to identify polypeptides. Inventions VIII/IX/X do not depend on Inventions XVIII/XIX to function and vice versa.

Inventions VIII/IX/X and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). Inventions VIII/IX/X are to a method of using a pharmaceutical composition in the manufacture of a medicament. Invention XX is to a transgenic or knockout non-human animal. Inventions VIII/IX/X do not depend on Invention XX to function and vice versa.

Inventions XI/XII/XIII and XIV/XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions XI/XII/XIII are to a method of treating a disease in a patient. Invention XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Inventions XI/XII/XIII do not depend on Invention XIV/XV to function and vice versa.

Inventions XI/XII/XIII and XVI/XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions XI/XII/XIII are to a method of treating a disease in a patient. Inventions XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease. Inventions XI/XII/XIII do not depend on Invention XVI/XVII to function and vice versa.

Inventions XI/XII/XIII and XVIII/XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions XI/XII/XIII are to a method of treating a disease in a

patient. Inventions XVIII/XIX are to a kit used to diagnose a disease and a kit to identify polypeptides. Inventions XI/XII/XIII do not depend on Inventions XVIII/XIX to function and vice versa.

Inventions XI/XII/XIII and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions XI/XII/XIII are to a method of treating a disease in a patient. Invention XX is to a transgenic or knockout non-human animal. Inventions XI/XII/XIII do not depend on Invention XX to function and vice versa.

Inventions XIV/XV and XVI/XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Inventions XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease. Inventions XIV/XV do not depend on Invention XVI/XVII to function and vice versa.

Inventions XIV/XV and XVIII/XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Inventions XVIII/XIX are to a kit used to diagnose a disease and a

kit to identify polypeptides. Inventions XIV/XV do not depend on Invention XVIII/XIX to function and vice versa.

Inventions XIV/XV and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Invention XX is to a transgenic or knockout non-human animal. Inventions XIV/XV do not depend on Invention XX to function and vice versa.

Inventions XVI/XVII and XVIII/XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease. Inventions XVIII/XIX are to a kit used to diagnose a disease and a kit to identify polypeptides. Inventions XVI/XVII do not depend on Invention XVIII/XIX to function and vice versa.

Inventions XVI/XVII and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease. Invention XX is to a transgenic or knockout non-human animal. Inventions XVI/XVII do not depend on Invention XX to function and vice versa.

Inventions XVIII/XIX and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions XVIII/XIX are to a kit used to diagnose a disease and a kit to identify polypeptides. Invention XX is to a transgenic or knockout non-human animal. Inventions XVIII/XIX do not depend on Invention XX to function and vice versa.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and that the search for one Invention is not required for the search of another, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is (571) 272-2911. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH